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EXAMINER

WEATHERBY, ELLSWORTH

ART UNIT	PAPER NUMBER
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3768

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07/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/799,094	Applicant(s) WANG ET AL.	
	Examiner Ellsworth Weatherby	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/22/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: Applicant first claims a biocompatible body and then claims the same body to be "the polymer body". There is no antecedent basis for the limitation, the polymer body. Therefore, Examiner is interpreting the claim as just the biocompatible body. Appropriate correction is required.
2. Claim 8 is objected to because of the following informalities: Applicant cites "the layers have a thickness". There is no antecedent basis for the limitation, the layers. Appropriate correction is required.
3. Claims 60-61 are objected to because of the following informalities: Applicant cites "at the location of said securing". This is not clear, therefore, for the purposes of examination the examiner is interpreting this as the marker at the location of said securing. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 17, 21, 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant refers to the radiopacity of stainless steel as a general standard of radiopacity. This is not clear claim language.

6. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant refers to 280 mg/l gadodiamine in 5000 ml blood as a standard of radiopacity. This is not clear claim language.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-3 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilles et al. (U.S. Patent No. 6,272,370).

Gilles et al. '370 teaches a medical device comprising: a biocompatible body and a marker secured to the polymeric, biocompatible body, the marker including a

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fluoroscopic imaging enhancement material and an MRI enhancement material (col. 25; lines 12-53). Gilles et al. '370 also teaches that the biocompatible body comprises a metal tip stabilizer (col. 28; lines 27-30). Gilles et al. '370 also teaches incorporating a paramagnetic material into a catheter (col. 22, lines 32-35).

9. Claims 7, 9-10, 12-14, 29, 38-41, 43-44, 47-48, 51-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Devens et al. (PGPub No. 2005/0124976).

Devens et al. '976 teaches a medical device comprising: a biocompatible body and a marker secured to the polymeric matrix, biocompatible body [0046], the marker including one or more separate layers carrying a marker for fluoroscopic imaging, MRI, and or ultrasound [0062]. It is interpreted that the concentric layers completely wrap around the body of the catheter (fig. 2a). Devens et al. '976 also teaches an innermost third layer in contact with the catheter body [0008]. Devens et al. '976 also teaches that the biocompatible body can be formed into a stent (claim 42). Devens et al. '976 also teaches a bonding layer [0007] and a drug delivery layer [0061].

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilles et al. '370 in view of MacDonald et al. (PGPub. No. 2007/0093142 A1).

Gilles et al. '370 teaches all the limitations of the claimed invention except for expressly teaching that the layers have a thickness of about 0.005 inch or less.

In the same field of endeavor, MacDonald et al. '142 teaches including a coating that has a thickness of about 1 micron or less [0175].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Gilles et al. '370 with MacDonald et al. '142. The motivation to modify Gilles et al. '370 with MacDonald et al. '142 would have been to minimize the layer's interaction with MRI induced fields, as taught by MacDonald et al. '142 [0175].

12. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Devens et al. '976 in view of Aita et al. (USPN 6,884,234 B2).

Devens et al. '976 teaches all the limitations of the claimed invention except for expressly teaching that the third layer is between the first and second layers.

In the same field of endeavor, Aita et al. '234 teaches a third layer that acts as a spacer between the first and second layers (col. 3, lines 1-13).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Devens et al. '976 with Aita et al. '234. The motivation to modify Devens et al. '976 with Aita et al. '234 would have been to allow for articulation of the device, as taught by Aita et al. '234 (col. 3, lines 1-13) or to insulate the layers.

13. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Devens et al. '976.

Devens et al. '976 teaches all the limitations of the claimed invention except for expressly teaching that the third layer defines the exterior surface of the marker. However, It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Devens et al. '976 to include a third layer that defines an exterior surface because it is old and well known in the art to provide a biocompatible coating for internal devices.

14. Claims 17-18 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devens et al. '976 in view of Dor et al. (USPN 6,334,871 B1).

Devens et al. '976 teaches all the limitations of the claimed invention except for expressly teaching that the MRI imaging enhancement material has a radiopacity of 0.9 or less the radiopacity of steel and that the MRI enhancement material has an atomic number of 40 or less.

In the same field of endeavor, Dor et al. '871 teaches using a material with radiopacity similar to steel to enhance or decrease radiopacity compared steel (claim 1, claim 5). Dor et al. '871 also teaches using a cobalt-chromium alloy (claim 13). Regarding claim 22, the examiner is interpreting the limitations of the claim to be met because both enhanced visibility over steel would have a MRI visibility about equal or greater than about 280 mg/ml gadodiamine in 5000 ml blood.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Devens et al. '976 with Dor et al. '871. The motivation to modify Devens et al. '976 with Dor et al. '871 would have been to use a material in varying thickness that would have less radiopacity than steel to improve imaging or visibility of the device.

15. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Devens et al. '976 in view of Dor et al. '871 as applied to claim 17 above, and further in view of MacDonald et al. '142.

Devens et al. '976 in view of Dor et al. '871 teaches all the limitations of the claimed invention except for expressly teaching that the layer including MRI enhancement material has a thickness of about 1 micron or less.

In the same field of endeavor, MacDonald et al. '142 teaches including a coating that has a thickness of about 1 micron or less [0175].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Devens et al. '976 in view of Dor et al. '871 with MacDonald et al. '142. The motivation to modify Devens et al. '976 in view of Dor et al. '871 with MacDonald et al. '142 would have been to minimize the layer's interaction with MRI induced fields, as taught by MacDonald et al. '142 [0175].

16. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Devens et al. '976.

Devens et al. '976 teaches all the limitations of the claimed invention except for expressly teaching that the MRI enhancement material is present at 25% or less by weight of the fluoroscopic imaging enhancement material. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Devens et al. '976 to include having the MRI enhancement material is present at 25% or less by weight of the fluoroscopic imaging enhancement material. The motivation to modify Devens et al. '976 would have been to apply the MRI enhancement layer as thin as possible to minimize interaction with MRI induced electromagnetic fields.

17. Claims 23-24 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devens et al. '976 in view of Stinson et al. (PGPub. No. 2005/0131522 A1).

Devens et al. '976 teaches all the limitations of the claimed invention except for expressly teaching that the fluoroscopic imaging material has a density of about 9.9 g/cc or more. Devens et al. '976 also does not expressly teach that the fluoroscopic material is pure metal, gold, platinum, tungsten, tantalum, rhenium, bismuth, silver, iridium and mixtures, compounds, complexes and mixtures thereof.

Stinson et al. '522 teaches using a layer on a stent that is about 14.9 g/cc [0079]. Stinson et al. '522 also teaches that the fluoroscopic material includes tantalum and stainless steel [0080].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Devens et al. '976 with Stinson et al. '522. The motivation to modify

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Devens et al. '976 with Stinson et al. '522 would have been to provide a clear fluoroscopic image of the device, as taught by Stinson et al. '522 [0079].

18. Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devens et al. '976 in view of Gellman et al. (PGPub. No. 2006/0111646 A1).

Devens et al. '976 teaches all the limitations of the claimed invention except for expressly teaching that the MRI material is ferromagnetic, paramagnetic, or superparamagnetic and that the material has a magnetic susceptibility of about 500×10^{-6} Emu or greater. Devens et al. '976 also does not expressly teach that the MRI material is selected from nickel, iron, magnesium, cobalt, gadodiamine, dysprosium, terbium and alloys, oxides and mixtures thereof.

In the same field of endeavor, Gellman et al. '646 teaches using paramagnetic and ferromagnetic materials as an MRI marker [0039]. Steel based compounds and gadolinium based compounds of varying thickness inherently would have a susceptibility of about 500×10^{-6} Emu or greater. Gellman et al. also teaches using gadolinium or iron based compounds for MRI detection [0040].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Devens et al. '976 with Gellman et al. '646. The motivation to modify Devens et al. '976 with Gellman et al. '646 would have been to provide enhanced MRI visibility.

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19. Claims 29-34, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devens et al. '976.

Devens et al. '976 teaches all the limitations of the claimed invention including that the biocompatible body is on a catheter or a balloon-catheter [0020] and that the marker extends over 70 to 85% of the body (fig. 2a). Devens et al. '976 also provides a polymer matrix for dispersing the marker materials [0046].

Devens et al. '976 does not expressly teach that the marker is noncircumferentially conducting. However, It would have been obvious to one of ordinary skill in the art at the time of the invention that suspending MRI or fluoroscopic markers in a polymer matrix would yield a noncircumferentially conducting layer for the purposes of preventing electrical or thermal conduction between the layers and the surrounding tissue.

20. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Devens et al. '976 as applied to claim 34 above, and further in view of Aita et al. '234.

Devens et al. '976 teaches all the limitations of the claimed invention except for expressly teaching that the device includes multiple markers secured to the biocompatible body at locations indicative of the location of a balloon carried by the balloon catheter.

Aita et al. '234 teaches an imagable balloon catheter that incorporates a balloon that has imagable materials on the interior wall of the balloon (claim 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Devens et al. '976 with Aita et al. '234. The motivation to modify Devens et al. '976 with Aita et al. '234 would have been to guarantee the location of the balloon catheter.

21. Claim 36-37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Devens et al. '976 in view of Stinson et al. '522.

Devens et al. '976 teaches all the limitations of the claimed invention including that the biocompatible body is a guidewire [0059]. Devens et al. '976 does not expressly teach that the guidewire is composed entirely of polymer at the location the marker is secured to the body.

In the same field of endeavor, Stinson et al. '522 teaches MR visible materials fused with polymer guidewires [0076].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Devens et al. '976 with Stinson et al. '522. The motivation to modify Devens et al. '976 with Stinson et al. '522 would have been to guarantee the location of the guidewire.

22. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Devens et al. '976 in view of Kucharczyk et al. (USPN 6,026,316).

Devens et al. '976 teaches all the limitations of the claimed invention except for expressly teaching that the MRI enhancement material is disposed within a ceramic matrix.

Kucharczyk et al. '316 teaches using MR visible ceramics in a catheter (col. 4, lines 16-35).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Devens et al. '976 with Kucharczyk et al. '316 to allow the device to be used in the presence of strong MRI magnetic fields.

23. Claims 11 and 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devens et al. '976 in view of Lee et al. (PGPub. No. 2005/0215885 A1).

Devens et al. '976 teaches all the limitations of the claimed invention except for expressly teaching that the body comprises 4-20 layers and that the layers have a thickness between about 0.00005 inches and 0.005 inches.

In the same field of endeavor, Lee et al. '885 teaches a MRI visible balloon catheter that has more than 4 layers (fig. 3). Lee et al. '885 also teaches that the wall thickness is about 40 micrometers [0024].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Devens et al. '976 with Lee et al. '885. The motivation to modify Devens et al. '976 with Lee et al. '885 would have been to provide a MR and or fluoroscopically visible catheter that provides improved thermal or electrical insulation without interfering with MR induced fields.

24. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Devens et al. '976.

Devens et al. '976 teaches all the limitations of the claimed invention except for expressly teaching that the system includes an inward-facing projection. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Devens et al. '976 to include an inward facing projection to carry a drug or marker to an internal site.

25. Claims 4-6, 55-59 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilles et al. '370 in view of Griffin et al. (USPN 2004/0193140 A1).

Gilles et al. '370 teaches all the limitations of the claimed invention except for expressly teaching that the markers are secured by crimping the marker onto the medical device, adhering the marker onto the medical device with glue.

In the same field of endeavor, Griffin et al. '140 teaches incorporating a radiopaque or MRI ring into a catheter by any suitable technique including crimping and adhesive bonding and thermal bonding [0056]. Griffin et al. '140 also teaches concentric layers that include radiopaque marker layers and MR visible layers [0033].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Gilles et al. '370 with Griffin et al. '140. The motivation to modify Gilles et al. '370 with Griffin et al. '140 would have been to use a well known technique bonding technique to incorporate diagnostic markers onto the catheter body.

26. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilles et al. '370 in view of Dor et al. '871.

Gilles et al. '370 teaches all the limitations of the claimed invention except for expressly teaching that the marker at the location of the securing has a radiopacity less than stainless steel.

In the same field of endeavor, Dor et al. '871 teaches using material with radiopacity similar to steel to enhance or decrease radiopacity compared steel (claim 1, claim 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Devens et al. '976 with Dor et al. '871. The motivation to modify Devens et al. '976 with Dor et al. '871 would have been to use a material in varying thickness that would have less radiopacity than steel to improve imaging or visibility of the device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ellsworth Weatherby whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

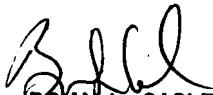
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EW


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